IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:

Wallace T. Ashton, et al.

Serial No.

10/542,214

July 14, 2005 Filed:

For: 3-AMINO-4-PHENYLBUTANOIC ACID DERIVATIVES AS DIPEPTIDYL PEPTIDASE INHIBITORS FOR THE TREATMENT OR PREVENTION OF DIABETES

OCT 1 7 2005

Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

To Be Assigned Art Unit:

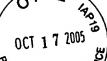
To Be Assigned Examiner:

INFORMATION DISCLOSURE STATEMENT **UNDER 37 CFR 1.97**

Sir:

- 1. In compliance with 37 C.F.R. 1.97, submitted on the attached form herewith is a list of patents, publications or other information which are requested to be made of record in this application. This Information Disclosure Statement is not an admission that any patent, publication or other information referred to herein is "prior art" for this invention. In accordance with 37 C.F.R. 1.97(h), the filing of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. 1.56(b).
- 2. In accordance with 37 C.F.R. 1.97(g), the filing of this Information Disclosure Statement shall not be construed to mean that a search has been made.
- Applicants respectfully request that the Examiner initial the attached form after reviewing the pertinence of each reference.
- Pursuant to 37 C.F.R. 1.98 (a)(2)(ii), copies of each cited U.S. patent and each U.S. patent application publication are not enclosed herewith.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on the date appearing below.



RMATION DISCLOSURE STATEMEN

5. Pucuant to 37 Co. R. 1.98(d), copies of references listed on the attached form that were submitted to or cited

by the Office in a related application upon which the instant application relies for an earlier filing date under 35 U.S.C. 120 are not enclosed. Related application(s) in which references were submitted to or cited by the Office are as follows:

	RELATED APPLICATION			
U. S. SERIAL NUMBER	FILING DATE	MERCK CASE		
10/540,283	June 20, 2005	21304YP		
10/537,476	June 3, 2005	21288YP		
10/530,215	April 4, 2005	21239YP		

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If th	If this is inconvenient, additional copies will be submitted upon request.								
	6. In accordance with 37 C.F.R. 1.97, (check one)								
\checkmark	the attached information is filed within three months of the filing date	of the captioned case.							
	the attached information is filed more than three months after the filin Office Action on the merits.	ng date but prior to the ma	ailing of a first						
	the attached information is filed before the mailing of a first Office act examination under §1.114.	tion after the filing of a red	quest for continued						
	the attached information is being filed more than three months after to Office Action on the merits, but before the mailing date of a Final Action otherwise closes prosecution in the application. The enclosed author Account No. 13-2755 for the fee required under 37 C.F.R. 1.17(p).	tion, Notice of Allowance,	or an action that						
	each item of information contained in this Information Disclosure Stater from a foreign patent office in a counterpart foreign application not measurement.								
	each item of information contained in the information disclosure state a foreign patent office in a counterpart application and this communic designated in §1.56(c) more than thirty days prior to the filing of the in	cation was not received b	y any individual						
	no item of information contained in this Information Disclosure Staten foreign patent office in a counterpart foreign application, and, to the k after making reasonable inquiry, was known to any individual designamenths prior to the filing of this Statement.	knowledge of the person s	signing the certification						
	By At Ro M Pa P.	y: Philippe L. Durette ttorney For Appli eg. No. 35,125 IERCK & CO., INC. eatent Dept., RY60-30 O. Box 2000	_						
	(7	lahway, N.J. 07065-0907 732)594- <u>4568</u> Pate: October 1 2 2005							

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INFORMATION DISCUSSURE	Application Number	10/542,214		
STATEMENT BY APPLICANT	Filing Date	July 14, 2005		
I / U\	First Named Inventor	Wallace T. Ashton, et al.		
OCT 17 2005 E	Group Art Unit			
(use as many sheets as necessary)	Examiner Name			
Sheet of 5	Attorney Docket Number	21317YP		

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	U.S. Patent Document Number	Kind Code (if known)	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
	1	6,699,871 B2		Edmondson et al.	03/02/2004			
	2	6,011,155		Villhauer	01/04/2000			
	3	6,166,063		Villhauer	12/26/2000			
	4	5,939,560		Jenkins et al.	08/17/1999			
	5	6,303,661 B1		Demuth et al.	10/16/2001			
	6	6,432,969 B1		Villhauer	08/13/2002			
	7	4,386,090		Moinet et al	05/31/1983			
	8	6,265,418		Kuroki et al.	07/24/2001			

FOREIGN PATENT DOCUMENTS							
Examiner Cite Initials* No.		Foreign Patent Document Office Number Kind Code (if known)			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	
	9	PCT	WO 03/082817 A2		MERCK & CO., INC.	10/09/2003	
	10	PCT	WO 03/000180 A2		MERCK & CO., INC.	01/03/2003	
	11	PCT	WO 03/000181 A2		MERCK & CO., INC.	01/03/2003	
	12	PCT	WO 03/000181 A3		MERCK & CO., INC.	01/03/2003	
	13	PCT	WO 02/076450 A1		MERCK & CO., INC.	10/03/2002	
	14	PCT	WO 2004/007468 A1		MERCK & CO., INC.	01/22/2004	
	15	PCT	WO 2004/032836 A2		MERCK & CO., INC.	04/22/2004	
	16	PCT	WO 2004/050022 A2		MERCK & CO., INC.	06/17/2004	
	17	PCT	WO 2004/058266 A1		MERCK & CO., INC.	07/15/2004	
	18	PCT	WO 2004/064778 A2		MERCK & CO., INC.	08/05/2004	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Examiner Signature Date Considered

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I	NFORMATION	DIS	CLOSURE	Application Number	10/542,214			
		7 A TO	DI ICANT	Filing Date	July 14, 2005			
S	TATEMENT BY	AP	PLICANI	First Named Inventor	Wallace T. Ashton, et al.			
				Group Art Unit				
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Sheet	2	of	5	Attorney Docket Number	21317YP			

U.S. PATENT DOCUMENTS								
Cite No.	U.S. Patent Document Number		Date of Publication					
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	Cite No.	Cite	U.S. Patent Document	U.S. Patent Document				

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No.	Foreign Patent Document Office Number Kind Code (if known)		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY			
	19	PCT	WO 2004/069162 A2		MERCK & CO., INC.	08/19/2004		
	20	PCT	WO 02/02560 A2		NOVO NORDISK A/S	01/10/2002		
	21	PCT	WO 01/96295 A2		NOVARTIS AG	12/20/2001		
	22	PCT	WO 01/96295 A3		NOVARTIS AG	12/20/2001		
	23	PCT	WO 01/34594 A1	N.	Guilford Pharmaceuticals, Inc.	05/17/2001		
	24	PCT	WO 00/34241		NOVARTIS AG	06/15/2000		
	25	РСТ	WO 98/19998 A2		NOVARTIS AG	05/14/1998		
	26	РСТ	WO 98/19998 A3		NOVARTIS AG	05/14/1998		
	27	PCT	WO 97/40832		Hansknoll-Institut Fur Naturstoff-Forschung E.V.	11/06/1997		
	28	PCT	WO 03/000180 A3		MERCK & CO., INC.	01/03/2003		

Examiner Signature Date Considered

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I	NFORMATION :	DIS	CLOSURE	Application Number	10/542,214
C	OF A OFFICE ALEXANDER BASE	AD		Filing Date	July 14, 2005
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	(use as many sheets	as n	ecessary)	Examiner Name	
Sheet	3	of	5	Attorney Docket Number	21317YP

U.S. PATENT DOCUMENTS								
Examiner Initials*	Cite No.	U.S. Patent Docum		Date of Publication of				

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document Office Number		Kind Code	Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY		
	29	PCT	WO 02/02560	(if known) A3	NOVO NORDISK	01/10/2002		
	30	PCT	WO 01/42262		AKZO NOBEL N.V.	06/14/2001		
	31	PCT	WO 2004/043940		MERCK & CO., INC.	05/27/2004		
_	32	PCT	WO 2004/007468		MERCK & CO., INC.	01/22/2004		
	33	PCT	WO 2004/110436		MERCK & CO., INC.	12/23/2004		
	34	PCT	WO 2004/112701	A2	MERCK & CO., INC.	12/29/2004		
	35	PCT	WO 2004/112701	A3	MERCK & CO., INC.	12/29/2004		
	36	PCT	WO 2005/011581	A2	MERCK & CO., INC.	02/10/2005		
	37	РСТ	WO 2005/044195	A2	MERCK & CO., INC.	05/19/2005		
	38	PCT	WO 2005/002530	A2	SMITHKLINE BEECHAM CORP.	01/09/2003		

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	DIS	SOSURE	Application Number	10/542,214		
	A TO	DI ICIANIT	Filing Date	July 14, 2005		
IAIEMENI BY	AP	PLICANI	First Named Inventor	Wallace T. Ashton, et al.		
		,	Group Art Unit			
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4	of	. 5	Attorney Docket Number	21317YP		
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U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No.	U.S. Patent Documen Number		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	

	FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No.	Foreign Patent Document Office Number		Kind Code (if known)	Name of Patentee or Applicant of Cited Document of Cited Document MM-DD-YYYY			
	39	PCT	WO 2005/056003	A1	GRAFFINITY PHARMACEUTICALS AG 06/23/2005			
	40	PCT	WO 2005/056013	A1	GRAFFINITY PHARMACEUTICALS AG 06/23/2005			
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Examiner Signature					Date Considered			

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· s	Substitute for form 1449B/PTO			COMPLET			
	INFORMATION DISCLOSURE			Application Number	10/542,214	11	
STATEMENT BY APPLICANT				Filing Date	July 14, 2005		
	STATEMENT B	Y AF	PLICANI	First Named Inventor	Wallace T. Ashton, et al.		
	,		,	Group Art Unit			
	(use as many shee	ets as n	necessary)	Examiner Name			
Shee	t 5	of	5	Attorney Docket Number	21317YP		

NON PATENT LITERATURE DOCUMENTS						
Examiner Initials*	Cite No.	Include name of the author, title, date, page(s), volume-issue number(s) and place of publication.				
	41	J. J. Holst, "Treatment of Type 2 Diabetes Mellitus with Agonists of the GLP-1 Receptor or DPP-IV Inhibitors", Expert Opin. Emerg. Drugs, Vol. 9(1) pp. 155-166, 2004.				
	42	C. F. Deacon, et al., "Inhibitors of dipeptidyl peptidase IV: A Novel Approach for the Prevention and Treatment of Type 2 Diabetes?", Expert Opin. Investig. Drugs, Vol. 13(9) pp. 1091-1102, 2004.				
	43	K. Augustyns et al., "Dipeptidyl Peptidase IV Inhibitors as New Therapeutic Agents for the Treatment of Type 2 Diabetes", Expert Opin. Ther. Patents, Vol. 13(4), pp. 499-510, 2003.				
	44	Novartis AG: WO0034241, "Novel N-substituted-2-Cyanopyrrolidines as Potent Inhibitors of Dipeptidyl Peptidase IV in the Treatment of Non-Insulin-Dependent Diabetes Mellitus", Exp. Opin. Ther. Patents, Vol. 10(12), pp. 1937-1942, 2000.				
	45	O. J. Orucker, "Therapeutic potential of dipeptidyl peptidase IV inhibitors for the treatment of type 2 diabetes", Exp. Opin Invest. Drugs, Vol.12, 2004, pages 87-100.				
	46	T. P. Vahl & D. A. D'Alessio, "Gut peptides in the treatment of diabetes mellitus" Exp. Opin. Invest. Drugs, Vol. 13, 2004, pages 177-188.				
	47	L. B. Knudsen, "Glucagon-like peptide-1: The Basis of a New Class of Treatment for Type 2 Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4128-4134.				
	48	Ann E. Weber, "Dipeptidyl Peptidase IV Inhibitors for the Treatment of Diabetes", J. Med. Chem, Vol. 47, 2004, pages 4135-4141.				
	49	J. J. Holst and C. F. Deacon, "Glucagon-like peptide 1 and inhibitors of dipeptidyl peptidase IV in the treatment of type 2 diabetes mellitus", Curr. Opin Pharmacology, Vol. 4, 2004, pages 589-596.				
	50	C. F. Deacon, "Perspectives in Diabetes - Therapeutic Strategies Based on Glucagon-Like Peptide 1", Diabetes, Vol. 53, Sept. 2004, pages 2181-2189.				
	51	Kuroki, et al, DAtabase CAPLUS on STN No. 130:1685654, 1999				
	52	Burger, A Guide to the Chemical Basis of Drug Design, page 15 (1983)				
L		l				

Examiner Signature	Date Considered	

^{*}Examiner: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.